Advising the Congress on Medicare issues

Follow-on biologics and Medicare

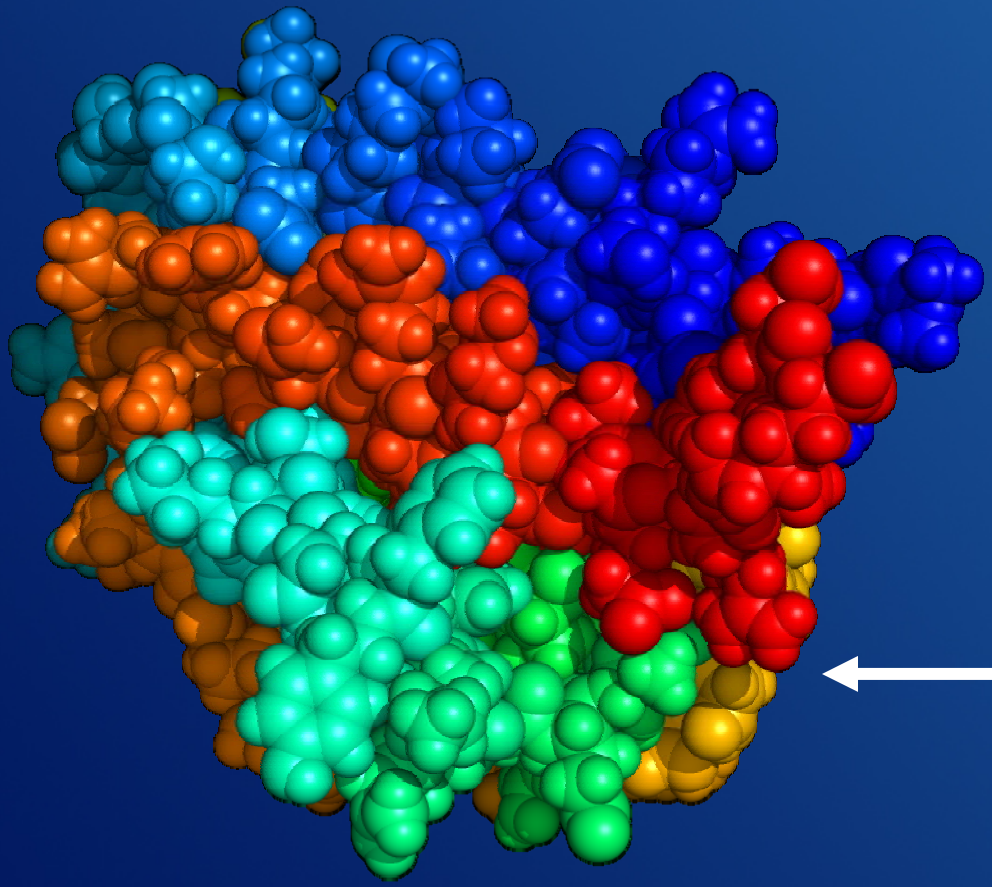
Joan Sokolovsky, Kim Neuman, and Nancy Ray

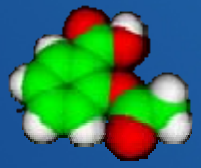
MEDPAC

Key issues

- Differences between biologics and drugs
- Patent system and FDA approval process
- Data exclusivity
- Comparability and interchangeability
- Follow-on biologics and Medicare payment systems
- Medicare payment systems and value

What is a biologic?





Small molecule drug: a drug synthesized via a chemical process (pictured: aspirin)

Biologic: medicinal product that is synthesized from a living organism or its products (pictured: EPO)

Differences between biologics and drugs affect the approval process for FOBs

- A follow-on biologic cannot be exactly identical to its reference product because of the large size and complexity of the molecules
- Biologics are more expensive to produce
- Biologics have specific safety risks

Patents are awarded by the Patent Office while FDA approves drugs for sale

- The Patent Office award patents based on utility, novelty, and nonobviousness
- FDA approves drugs on the basis of their safety and efficacy
- Innovators apply for patent protection before the FDA approves their product
- Patent protection occurs concurrently with FDA approval process

FDA approval triggers data exclusivity period

- Data exclusivity is the period before a manufacturer can apply for FDA approval using the innovator's data on safety and efficacy
- Data exclusivity and patent protection often run concurrently
- Analysts disagree about how long a period of data exclusivity is necessary
- Some argue for a long period of data exclusivity to recoup development costs
- Others contend that lengthy exclusivity periods would delay entry of low-cost alternatives and reduce manufacturers' incentive to innovate

FDA must determine that an FOB and innovator are comparable to approve FOB

- Comparability means that the safety, identity, purity, and potency of the FOB is unchanged from the reference product
- FDA uses case-by-case comparability protocols to approve changes to innovator biologics
- Analysts disagree on whether FDA should use this process to approve FOBs

FDA might also be given authority to determine interchangeability

- Interchangeability means that an individual patient can switch back and forth between products with no clinical effect
- Analysts dispute whether the science currently exists to demonstrate interchangeability
- Most agree that comparability, not interchangeability, is needed for approval

Biologics play a large role in Medicare Part B

- Top 6 Part B biologics account for $7 billion (43%) of Part B drug spending in 2007:
  - Epoetin alfa $2.6 billion
  - Darbepoetin alfa $1.3 billion
  - Rituximab $1.1 billion
  - Bevacizumab $0.8 billion
  - Infliximab $0.8 billion
  - Pegfilgrastim $0.8 billion
- FOBs offer the potential for savings on Part B drugs
- The amount of savings will depend in part on how FOBs are treated under the Part B payment system

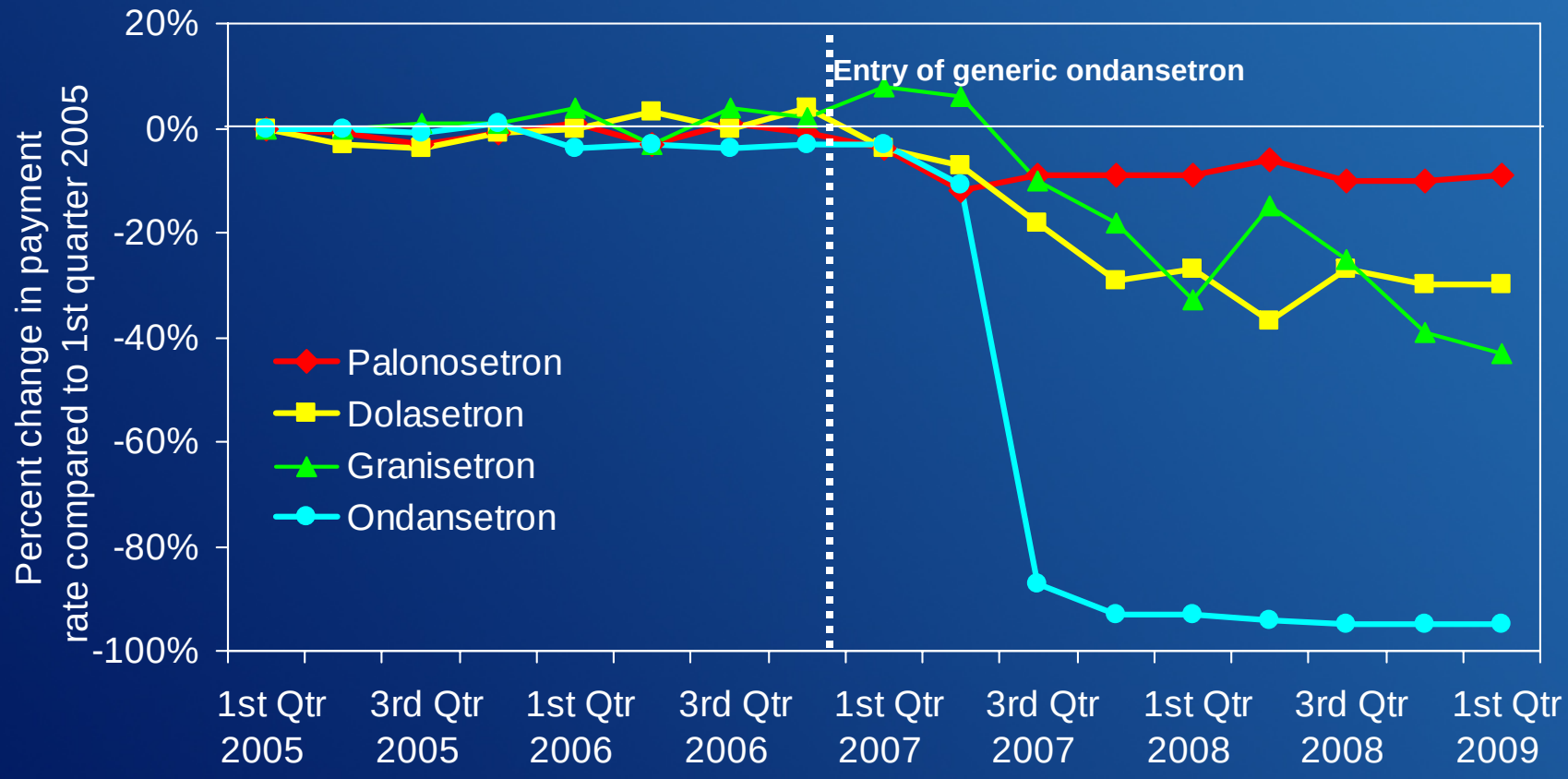
Medicare Part B payment system

- Most Part B drugs are administered by physicians
- Medicare pays physicians 106% of a drug's ASP
- ASP is the manufacturer's average price for sales to all purchases net of rebates, discounts, and price concessions
- Physicians have the incentive to seek the lowest price available for a product since they are paid 106% of ASP regardless of their acquisition costs

How billing codes factor into payment rates and affect competition

- All products in same code receive same payment rate
- Generic and brand versions of a drug are in same code
- MMA requires biologics and single source drugs to be paid based on their own ASP; each has its own code
- Exception for a small number of closely related biologics and single source drugs that were in the same code prior to MMA

Impact of generic entry on Medicare payment rates for a class of IV antiemetic drugs



Source: MedPAC analysis Medicare average sales price payment rate quarterly files from CMS.

Implications of FOB coding for Part B

- Same code would lead to more competition and maximize savings
- Considerations of clinical appropriateness

Possible coding approaches for FOBs and innovator biologics

- Make placement in the same billing code contingent on an FDA determination of interchangeability
- Permit the Secretary to place FOBs and innovator biologics in the same code after input from an advisory committee of scientific experts or a public comment process
- Require FOBs and innovator biologics to be placed in same billing code, but permit the Secretary to make exceptions if evidence shows that this is not clinically appropriate for particular products

Medicare's rate-setting process

- In most instances, Medicare sets payment rates without considering clinical evidence. Thus, Medicare may:
  - Pay different rates for services that are clinically comparable
  - Pay more for a service without clinical evidence showing that it is better than currently available treatments
- Some policy experts have concluded that Medicare needs more flexibility to become a more active payer

Innovative pricing strategies would improve the value of Medicare spending

- Reference pricing strategies:
  - Set a service's payment rate based on the rate of the least costly, clinically comparable service
- Performance-based strategies
  - Pay only when a service works—"payment by results"
- Bundling strategies
  - Create payment bundles for groups of clinically associated items and services

For discussion

- Questions about concepts including: FOBs, Medicare's coding policies, Medicare's rate-setting process
- Future areas for research
- Next steps
  - April discussion of FOBs and Part D
  - June 2009 chapter that discusses issues concerning FOBs